

REMARKS

Claims 10-15 are pending in this application. Claim 10 been amended. No new matter has been introduced.

Claims 10, 11 and 13-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Grooms (Int. Application Pub. WO 99/21515) ("Grooms") in view of WO 97/37595 to Pedlick et al. ("Pedlick"). This rejection is respectfully traversed.

The claimed invention relates to an implant for cross-pin anterior cruciate reconstruction surgery. As such, amended independent claim 10 recites an "implant for cross-pin anterior cruciate reconstruction surgery" comprising "a proximal end," "a tapered distal end . . . terminating in a pointed tip" and "a transverse eye for receiving a flexible strand to draw said implant into an opening in bone." Amended independent claim 10 further recites that the transverse eye communicates with "longitudinal channels formed on opposite sides of the implant and extending from the transverse eye to the tip in a direction aligned with the longitudinal axis of the distal end." Amended independent claim 10 also recites "a solid rigid cylindrical shaft . . . having a smooth cylindrical outer surface for supporting a graft in said opening in bone, the entire smooth cylindrical surface being parallel to a longitudinal axis of the shaft."

Grooms relates to a "unitary bone implant (200) having at least one rigid, mineralized bone segment (201, 202), which may be machined to include threads, grooves, a driver head, a recess or a symmetric or asymmetric shape, and a flexible, demineralized segment (203), which may also be machined to any desired shape prior to demineralization, or after demineralization." (Abstract).

Pedlick relates to a "suture anchor . . . having an annular displaced corner and abutment wall which act to seat the suture anchor firmly within a bore hole in substrate." (Abstract). According to Pedlick, "the suture anchor comprises a substantially wedge-shaped body having a smaller distal end and a larger proximal end, means (330A) thereon for retaining a suture (500), and means thereon for releasable connection to an inserter shaft." (Abstract).

Grooms and Pedlick, whether considered alone or in combination, fail to disclose, teach or suggest all limitations of amended independent claim 10 and of dependent claims 11 and 13-15. Grooms fails to disclose, teach or suggest "a solid rigid cylindrical shaft," much less "a solid rigid cylindrical shaft . . . having a smooth cylindrical outer surface for supporting a graft in said opening in bone, the entire smooth cylindrical surface being parallel to a longitudinal axis of the shaft," as amended independent claim 10 recites. Grooms teaches a "flexible, demineralized segment (203)" (which would arguably correspond to the "cylindrical shaft" of the claimed invention) and not a "rigid cylindrical shaft."

In addition, demineralized segment (203) of Grooms is flexible and has a wavy, serpentine configuration, and not "a smooth cylindrical outer surface . . . parallel to a longitudinal axis of the shaft," as in the claimed invention. Applicant submits that demineralized segment (203) of Grooms (which would arguably correspond to the "shaft" of the claimed invention) is not "disposed between, and extending completely from, said proximal end to said tapered distal end," as claim 10 recites. Thus, "the entire smooth cylindrical outer surface" of demineralized segment (203) of Grooms is not "parallel to a longitudinal axis of the shaft."

Grooms also fails to disclose, teach or suggest "a transverse eye . . . communicating with longitudinal channels formed on opposite sides of the implant and extending from the transverse eye to the tip in a direction aligned with the longitudinal axis of the distal end," as claim 10 recites. Grooms does not disclose or illustrate any channels in communication with an eye, much less in communication with a transverse eye.

In the Office Action dated May 31, 2007, the examiner asserts that "the shaft shown in figure 2 of Grooms is clearly cylindrical" explaining that the "drawing is only wavy to show the flexibility of the shaft, but it still maintains a cylindrical cross-section." (May 31, 2007 Office Action at 4). Applicants disagree with this assertion. First, if the demineralized segment (203) of Grooms would have been "clearly cylindrical" (as the examiner asserts), then this structure would had to be described in the specification (and illustrated in the drawings) of Grooms -- which it had not been. Second, the fact that demineralized segment (203) of Grooms has a cylindrical cross-section does not equate the limitation of claim 1 that "the entire smooth cylindrical outer surface [be] parallel to a longitudinal axis of the shaft." The shaft of Grooms simply does not have an entire smooth cylindrical outer surface parallel to a longitudinal axis of the shaft.

Pedlick fails to address the deficiencies of Grooms. Pedlick does not disclose, teach or suggest an "implant for cross-pin anterior cruciate reconstruction surgery" comprising "a tapered distal end" and "a transverse eye extending through the tapered distal end for receiving a flexible strand to draw said implant into an opening in bone," as amended independent claim 10 recites. Pedlick teaches that "the suture anchor can comprise a substantially wedge-shaped body having a smaller distal end and a larger proximal end, *the body defining a hole therethrough for retaining a suture*" (page 6, lines 16-18;

emphasis added). In fact, Pedlick specifically emphasizes that “suture opening 5 is defined by the body of the suture anchor 1” (page 16, lines 12-13) to allow suture 10 to pass “through the opening 5” (page 17, line 2). Pedlick also illustrates first abutment end 2 and second abutment end 3 (which would arguably correspond to the “tapered distal end” of the claimed invention) without suture opening 5 provided therethrough. Opening 5 extends through the smooth, cylindrical untapered body of Pedlick, not through the tapered ends. Accordingly, Pedlick fails to disclose or suggest “a transverse eye extending through the tapered distal end,” as recited in amended claim 10 of the present application.

Pedlick also fails to disclose a transverse eye “communicating with longitudinal channels formed on opposite sides of the implant and extending from the transverse eye” as claimed. The Examiner asserts that Pedlick teaches “a channel formed around the hole extending to the tip, in order to guide the suture thread into the hole shown best in figures 13 and 5.” However, a channel formed around the hole is a circular channel, not a longitudinal channel. Moreover, the circular “channel” of Pedlick does not “extend[] completely from the transverse eye to the tip in a direction aligned with the longitudinal axis of the [tapered] distal end” as recited in claim 1. The tapered distal ends of Pedlick are at the top and bottom of Fig. 5. Clearly, the circular channel of Pedlick does not extend from the eyelet to these ends.

Applicants further submit that a person of ordinary skill in the art would not have been motivated to combine the teachings of Grooms with those of Pedlick. Grooms relates to a bone implant having a rigid, mineralized bone segment that can be machined to include threads or grooves, and a flexible, demineralized segment formed by exposing the implant to a HCl solution, for example. Grooms teaches that the demineralized segment has “sufficient flexibility to act as a ligament, tendon, or flexible support” (claim

3). In contrast, the crux of Pedlick is a suture anchor with a substantially wedge-shaped body. The wedge-shaped suture anchor of Pedlick has a specific configuration that allows it to be introduced into a bore in the bone by an inserter shaft, and to further be rotated within the bore so that edges of the anchor body engage walls of the bore. Accordingly, one skilled in the art would not have been motivated to combine the bone implant of Grooms, which has a demineralized segment that acts as a ligament or tendon between two body parts, with the suture anchor of Pedlick, which is designed to retain suture and which has a specific configuration that allows it to rotate within a bore.

For at least the reasons above, the Office Action fails to establish a *prima facie* case of obviousness, and withdrawal of the rejection of claims 10, 11 and 13-15 is respectfully requested.

Claim 12 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Grooms in view of Pedlick and further in view of Grooms et al. (U.S. Patent No. 6,045,554) ("Grooms '554"). This rejection is respectfully traversed.

Claim 12 depends on amended independent claim 10 and recites that "the implant is formed of synthetic bone material."

Grooms '554 relates to an interference screw provided "by machining a fragment of autograft or allograft cortical bone from a donor or from a recipient's amputated bone." (Abstract). Grooms '554 teaches that the interference screw "has a machined pointed, rounded or flush end and an opposite machined end which mates with a drive means, and has advantages over conventional interference screws known in the art in that subsequent

to implantation, no residual hardware that must later be removed remains at the implant site.” (Abstract).

The subject matter of claim 12 would not have been obvious over Grooms in view of Pedlick and Grooms '554. None of the cited references, considered alone or in combination, discloses, teaches or suggests the subject matter of amended independent claim 10 and of dependent claim 12. As noted, Grooms and Pedlick, considered alone or in combination, do not disclose or suggest all limitations of amended independent claim 10.

Grooms '554 fails to rectify the deficiencies of Grooms and Pedlick. Grooms '554 teaches an interference screw formed from a machined fragment of cortical bone, and not an “implant for cross-pin anterior cruciate reconstruction surgery” having “a tapered distal end . . . terminating in a pointed tip” and “a transverse eye for receiving a flexible strand to draw said implant into an opening in bone, said transverse eye extending completely through said tapered distal end in a direction transverse to the longitudinal axis of the distal end,” as claim 10 recites. Grooms '554 is also silent about “a solid rigid cylindrical shaft . . . having a smooth cylindrical outer surface for supporting a graft in said bone, the entire smooth cylindrical surface being parallel to a longitudinal axis of the shaft,” as in the claimed invention. As illustrated in FIG. 5D of Grooms '554, the screw after machining is provided with “screw thread 22,” and not with “a smooth cylindrical outer surface,” as recited in claim 10. For at least these reason, the Office Action fails to establish a *prima facie* case of obviousness, and withdrawal of the rejection of claim 12 is also respectfully requested.

Allowance of all pending claims is solicited.

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